



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 20 1999

7048 '99 AUG 23 P1:16

Mr. Larry Simns, President
The Maryland Watermen's Association, Inc.
1805A Virginia Street
Annapolis, Maryland 21401

Dear Mr. Simns:

Thank you for your recent inquiry to Senator Barbara A. Mikulski, regarding the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest. Senator Mikulski has asked us to respond directly to you. As you may know, FDA published a request for comments on this petition in the Federal Register of January 21, 1999. We have enclosed a copy for your reference.

You oppose the petition and encourage FDA to work with the Interstate Shellfish Sanitation Conference in addressing this proposal.

We appreciate you bringing your comments to our attention and we have entered them into the Administrative Record for this petition. Your comments will be reviewed in the Agency's deliberations on this petition.

We trust this information responds to your concerns.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

Enclosure
Federal Register, January 21, 1999

98P-0504

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C266 /Ans

Page 2 - Mr. Larry Simms, President

cc: The Honorable Barbara A. Milkulski
United States Senate
Washington, D.C. 20510-2003

Dockets Management Branch ✓
(Docket No. 98P-0504)

BARBARA A. MIKULSKI
MARYLAND

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United States Senate
WASHINGTON, DC 20510-2003

July 29, 1999

Ms. Diane Thompson
Assoc. Commissioner for Legislative Affs.
Dept. of Health & Human Services
Food and Drug Administration
5600 Fishers Ln. 1555 Parklawn Bldg.
Rockville, Maryland 20857

Dear Diane:

I am writing to request your consideration of the attached correspondence from Mr. Larry Simns. Please respond directly to Mr. Simns and send a copy to Ms. Emily Gilbert of my staff. If you have any questions, please call Ms. Gilbert at (202) 224-4654.

Thank you for your assistance.

Sincerely,



Barbara A. Mikulski
United States Senator

BAM:efg
Enclosure

No. 99- 5247

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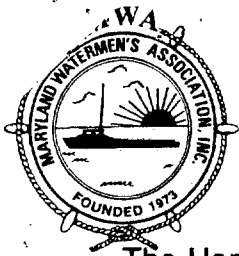
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The Maryland Watermen's Association, Inc.

The Honorable Barbara Mikulski
United States Senator
709 Hart Senate Office Building
Washington, DC 20510

Dear Senator Mikulski:

For your information I am enclosing correspondence from the Louisanna Gulf Oyster Industry Task Force concerning proposed regulations on the shellfish industry by the FDA.

As you can see from the attached Post Harvest Treatment Issue Fact Sheet any independant regulations concerning the shellfish industry falls outside the work being done by the Interstate Shellfish Sanitation Conference (ISSC) on which I sit as an industry representative on the Board of Directors.

The proposed regulations would in effect take away the choice of the consumer to enjoy fresh, unprocessed raw oysters. These proposed regulations which would require pasteurization or post treatment of all raw product is primarily directed at the warm water states, but if it is imposed on the southern states, in a very short period of time Maryland will be affected even though the concerns that prompted this action are not present here.

I am also enclosing a draft resolution for your further information on this issue along with the postcard designed to go to FDA from the industry this action would harm.

We are most concerned about FDA responding to a special interest group such as the Center for Science in the Public Interest (CSPI) and in so doing trying to circumvent the ISSC.

Any assistance you can give us in contacting the FDA to leverage them to withdraw the proposed regulations is much needed and would be most appreciated.

Sincerely

Larry Simns
President

LS/me

Enclosures

cc: The Honorable Paul Sarbanes
Food and Drug Administration

POST HARVEST TREATMENT ISSUE FACT SHEET

- America's molluscan shellfish industry has long been regulated by the Interstate Shellfish Sanitation Conference (ISSC), an independent body comprised of state health regulators and other public health experts. Advisors to ISSC include industry representatives and the US Food and Drug Administration (FDA) itself.
- This independent regulatory approach has existed for nearly 15 years by virtue of a Memorandum of Understanding between FDA and the ISSC, and has served the interests of all parties fairly.
- Currently a self-appointed "consumer watchdog group" the Center for Science in the Public Interest (CSPI) has declared war on both the industry and ISSC, urging FDA to drop its long-standing agreement with the ISSC by mandating post harvest treatment or pasteurization of fresh oysters intended for raw consumption. While CSPI claims they seek to impose these rules only in so-called "warm water states", the extensive petition filed by CSPI regarding these rules does not limit where or when mandatory post-harvest treatment should occur.
- CSPI claims that America's consumers are at risk from a naturally occurring bacteria known as *Vibrio vulnificus* which is sometimes found in shellfish. Their claims of illnesses related to *V. vulnificus* are greatly suspect and are questioned by most public health and all industry organizations. In reality, risks from *V. vulnificus* are limited exclusively to persons with certain pre-existing conditions most prominently, liver disease.
- However, even supporters of these proposed rules will admit that as few as only 1 in 20,000 people in the "at risk" category are susceptible to illness from shellfish *V. vulnificus*!
- Under the guidance of ISSC and upon the initiative of individual states working in concert with industry, a campaign of consumer education and awareness is working. While the magnitude of the campaign varies from state to state, depending as it should on shellfish consumption, the results have been excellent and have greatly reduced serious illnesses and deaths by alerting those with pre-existing conditions of possible risks.
- ISSC and most state public health bodies believe that consumer education is an intelligent, measured and appropriate response to health concerns and fully support continuing both the education campaigns and ISSC authority on the issue.
- Only one company manufactures the technology available to achieve CSPI's dubious goals. The equipment costs approximately \$800,000 per unit and is licensed for \$250,000 plus a royalty of 2 cents per treated oyster. The company selling this process estimates that the cost of treatment will raise dockside prices by 6-8 cents per oyster—effectively doubling today's cost!
- This much higher cost will result in lower consumer demand, which will then drive prices down and drive many oyster harvesters out of business.
- Moreover, many restaurant owners and consumers have rejected treated oysters as being of poor taste and poor quality, further reducing consumer demand.
- America's consumers deserve choice of product—treated and untreated—if the market shows a desire for both.

DRAFT RESOLUTION

WHEREAS, Oysters and other shellfish are a treasured treat for millions of Americans in every state; and

WHEREAS, The American consumer has always enjoyed a fundamental choice between products of all types; and

WHEREAS, Personal responsibility and care for one's own health and well-being are commonly agreed upon tenets of American life; and

WHEREAS, Important emerging technologies are now making it possible for consumers of oysters and other shellfish products to choose between traditional raw shellfish products and "treated" or pasteurized shellfish products in a competitive free market environment, and

WHEREAS, It is widely accepted by all parties involved that "treated" oysters will both fundamentally change the condition of raw shellfish, and that such treatment raises the wholesale price of oysters from the current price of approximately eight cents apiece by another six to eight cents apiece, and

WHEREAS, It is reasonable to expect in a free market economy that these higher prices will then be passed along to the consumer, resulting in lower demand for oysters, and

WHEREAS, America's shellfish industry is heavily populated by small self-employed harvesters and leaseholders already operating on limited incomes, and

WHEREAS, Lower consumer demand could further threaten the small shellfish industry and the livelihoods of thousands of area residents and families who are dependent on oyster harvesting and processing for their own well-being, and

WHEREAS, The U.S. Food and Drug Administration has been asked to consider new rules which would force costly and unnecessary post-harvest treatment of oysters, placing product from our area at a severe competitive disadvantage on the open market against product from other regions which will not be required to be treated in the same expensive manner, and

WHEREAS, America's oyster and shellfish industry has worked cooperatively and with great success to educate consumers with certain health conditions and risks which may be affected by certain types of shellfish, and

WHEREAS, These education efforts have been highly successful in reducing health impacts when they have been allowed to fully flourish, and

Now, therefore, BE IT RESOLVED, that a copy of this resolution be forwarded to the U.S. Food and Drug Administration, our Congressional delegation, the Governor and other state elected officials, and

BE IT FURTHER RESOLVED that the (name of organization / body) does hereby encourage the U.S. Food and Drug Administration to reject these costly and unnecessary rules and regulations in favor of continuing its successful work with America's shellfish industry toward greater consumer education and awareness, and toward the continuation of a competitive market economy system which has served America's consumers well since the founding of our nation.